

<b>Interview Summary</b>	Application No.	Applicant(s)	
	10/542,969	SUGA ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) Hasan S. Ahmed. (3) Albert Jacobs.  
 (2) Humera Sheikh. (4) \_\_\_\_\_.

Date of Interview: 03 January 2008.

Type: a) ☐ Telephonic b) ☐ Video Conference  
 c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.  
 If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 6 and 7.


Identification of prior art discussed: N/A.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Examiners indicated that the proposed language "substantially completely" may pose potential 112(1) new matter and 112(2) issues. Applicant's representative indicated that said language is inherent in the disclosure, rather than explicitly stated.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

  
 HUMERA N. SHEIKH  
 PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

\_\_\_\_\_  
 Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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170 Park Avenue New York, New York 10022  
Telephone (212) 328-6100 Facsimile (212) 328-6101  
Los Angeles • Stamford • Albany  
www.dreierllp.com

## FAX COVER SHEET

Date: December 13, 2007

NAME	COMPANY	FAX NO.	TEL. NO.
Patent Examiner Mr. Hassan Ahmed	United States Patent and Trademark Office	571-273-4792	

FROM: Albert L. Jacobs, Jr.

DIRECT DIAL: 212-710-5963

E-mail

ajacobs@dreierllp.com

## Message:

The attached draft Amendment is offered to the Examiner for discussion purposes.

Thank you.

No. of Pages (including cover sheet): 7

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If you have any difficulties receiving this transmission, please call (212) 328-6100

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Atty Docket No: 602129.001

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**In re Application of:** Tomoharu Suga et al.

**ART UNIT:** 1615

**SERIAL NO.:** 10/542,969

**EXAMINER:** Ahmed, Hasan Syed

**FILED:** July 21, 2005

**FOR:** INTRAORALLY RAPIDLY DISINTEGRATING TABLETS AND THEIR  
PRODUCTION

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**AMENDMENT**

**DRAFT**

Commissioner for Patents  
P.O. Box 1450  
**Mail Stop Amendment**  
Alexandria, VA 22313-1450

SIR:

In response to the Office Action mailed September 7, 2007 please amend the above-identified application as follows:

**Change the Title** to read as set forth above;

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks** begin on page 4 of this paper.

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Atty. Docket No.:602129.001

**AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listing, of claims in this application.

Please cancel claim 1.

2. (Currently Amended ) The intraorally rapidly disintegrating tablet according to claim +6, wherein the pharmaceutically acceptable disintegrating agent is a compound selected from the group consisting of crystalline cellulose, low-substituted hydroxypropyl cellulose, carboxymethyl cellulose, calcium carboxymethyl cellulose, crospovidone and starch represented by potato starch, wheat starch, corn starch, rice starch, hydroxypropyl starch, sodium carboxymethyl starch, and partial-pregelatinized starch.

3. (Currently Amended) The intraorally rapidly disintegrating tablet according to claim +6, wherein the sugar is selected from the group consisting of sugar alcohol represented by mannitol, xylitol, sorbitol, erythritol, maltitol and maltose; lactose, sucrose, glucose, and oligosaccharide.

4. (Currently Amended) The intraorally rapidly disintegrating tablet according to claim +6, wherein the average particle diameter of the coated-granules is in the range of 20 to 1000µm.

5. (Currently Amended) The intraorally rapidly disintegrating tablet according to claim +6, wherein the thickness of the tablet is in the range of 1 to 10mm.

6. (New) An intraorally rapidly disintegrating tablet which comprises:

an active ingredient mixed with at least one sugar to form a core and a coating of a pharmaceutically acceptable disintegrating agent substantially completely covering said core to form a granule.

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7. (New) An intraorally rapidly disintegrating tablet which comprises:  
a water soluble active ingredient which constitutes a core and a coating of a  
pharmaceutically acceptable disintegrating agent substantially completely covering said  
core to form a granule.
8. (New) The intraorally rapidly disintegrating tablet according to claim 7, wherein the  
pharmaceutically acceptable disintegrating agent is a compound selected from the group  
consisting of crystalline cellulose, low-substituted hydroxypropyl cellulose, carboxymethyl  
cellulose, calcium carboxymethyl cellulose, crospovidone and starch represented by potato  
starch, wheat starch, corn starch, rice starch, hydroxypropyl starch, sodium carboxymethyl  
starch, and partial-pregelatinized starch.
9. (New) The intraorally rapidly disintegrating tablet according to claim 7, wherein  
the average particle diameter of the granules is in the range of 20 to 1000µm.
10. (New) The intraorally rapidly disintegrating tablet according to claim 7 wherein  
the thickness of the tablet is in the range of 1 to 10mm.

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**REMARKS**

The Examiner has rejected claims 1-5 as anticipated by Mizumoto et al., U.S. Patent No. 5,576,014. The Examiner has alleged that Mizumoto discloses an intraorally rapidly disintegrating tablet which is alleged to have the features of the claimed invention. It is believed that new independent claims 6 and 7 clearly point out and define applicant's invention in a manner that will assist the Examiner's understanding that applicant's invention is different from the Mizumoto disclosure. New claim 6 specifies an intraorally rapidly disintegrating tablet which comprises an active ingredient mixed with at least one sugar to form a core. The core is coated with a pharmaceutically acceptable disintegrating agent which substantially completely covers the core to form a granule. New claim 7 specifies an intraorally rapidly disintegrating tablet which comprises a water soluble active ingredient which constitutes a core and a coating of a pharmaceutically acceptable disintegrating agent which substantially completely covers the core to form a granule. As the Examiner recognized on page 4 of the Official Action, Mizumoto describes that an active agent may be mixed with a saccharide and other additives and that this mixture may then be coated with an aqueous solution of high moldability saccharide. Mizumoto then goes on to suggest that this aqueous solution of highly moldable saccharide can be used to coat the core and that this highly moldable saccharide aqueous solution can also contain a disintegrant. The claims before the Examiner clearly distinguish applicant's invention from Mizumoto.

According to applicant's invention as claimed, the disintegrating agent is a coating which substantially completely covers the core. In new claim 6, the core is defined as an active ingredient mixed with at least one sugar. In new claim 7, the core is defined as a water soluble active ingredient. The purpose of a disintegrating agent is to facilitate rapid disintegration of the

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tablet. It achieves this by loosening adhesion between the granules constituting the tablet by absorbing water, thereby causing swelling.

According to Mizumoto at column 7 beginning at about line 19, the active ingredient is mixed with a low moldability saccharide. Alternatively, the active ingredient is mixed with granules obtained by granulating a low moldability saccharide with a high moldability saccharide. A further alternative is granulating a low moldability saccharide with both an active agent and a high moldability saccharide in any order. A further alternative is coating a low moldability saccharide with a high moldability saccharide and then with an active ingredient providing a second layer and granulating the resulting product with a high moldability saccharide. Lastly, Mizumoto describes a step of coating a low moldability saccharide with an active ingredient and granulating the coated product with a high moldability saccharide. All of these products clearly and succinctly differ from applicant's product which comprises a core substantially completely covered with a disintegrating agent. It is the fact that the core is substantially completely covered with disintegrating agent which provides the rapid disintegration of the tablet according to applicant's invention.

When Mizumoto describes in column 13 lines 58-65 mixing an active ingredient with a low moldability saccharide and then preparing a coating solution by dissolving the active ingredient with a high moldability saccharide in water, there is no suggestion of substantially completely covering a core in a non-aqueous state with a disintegrant. It is moreover believed that if Mizumoto added a disintegrant to the coating solution, it would not perform the function performed by the disintegrating agent of the present invention. It is the disintegrating agent itself which substantially completely covers the core and thereby provides rapid disintegration of the tablet. Thus, one skilled in the art would not add a disintegrating agent to the coating solution of

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Mizumoto because it would defeat the purpose of using a disintegrating agent. The disintegrating agent would absorb water from the coating solution and thus cease to function as a disintegrating agent. Therefore, there is no basis for suggesting that one of ordinary skill in the art would read Mizumoto as suggesting that a disintegrating agent should instead be used to substantially completely coat the core as applicants have claimed. It is believed, therefore, that Mizumoto clearly teaches away from the invention as now clearly and succinctly defined by the claims before the Examiner, particularly new independent claims 6 and 7 and the claims which depend therefrom.

It is clear therefore that applicant's claims 6, 2-5 and 7-10 distinguish his invention from that of the cited reference and allowance on reconsideration is believed to be in order and is respectfully requested.

Respectfully submitted,

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Albert L. Jacobs, Jr.  
Reg. No. 22,211  
Attorney for Applicant  
DRIER LLP  
499 Park Avenue  
New York, NY 10022  
Tel : (212) 328-6000  
Fax: (212) 328-6001

Dated: December 13, 2007

*Customer No. 61834*